K081258
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5. 510(K) SUMMARY

JAN - 6 2009

Applicant:

Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765
USA
Phone: +1-800-729-7272
Fax: +1-909-839-8804

Date: May 1, 2008

Contact Person:

Natalie Bennington
Manager, Regulatory Affairs

Proprietary Device Name: Lasso 2515 NAV Variable Catheter, D-1290-01 & D-1290-02

Common Device Name: Electrophysiologic Mapping Catheter

Classification Name: Electrode Recording Catheter
(per 21 CFR 870.1220, Product Code DRF)

Predicate Devices:

1. Variable Lasso 2515 Circular Mapping Catheter [510(k) K031161]
2. Star Diagnostic Catheter ([510(k) K954390] (later renamed NaviStar Diagnostic Catheter)

Manufacturer:

Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Manufacturing Sites:

Biosense Webster Inc.
15715 Arrow Highway
Irwindale, CA 91706

Biosense Webster, Inc.
Cordis de Mexico
Circuito Interior Norte #1820
Parque Industrial Salvarcar 32599
Juarez, Chihuahua, Mexico

5.1 Substantially Equivalent To:

The Biosense Webster, Inc. Lasso 2515 NAV Variable Catheter is substantially equivalent to the Biosense Webster Variable Lasso 2515 Circular Mapping Catheter [510(k) K031161, cleared July 22, 2003] and the Biosense Webster NaviStar Diagnostic Catheter [510(k) K954390, cleared Dec. 21, 1995].

5.2 Description of the Device Subject to Premarket Notification:

The LASSO 2515 NAV Variable Catheter has been designed to facilitate electrophysiological mapping of the atria of the heart with the Carto 3 Navigation System and a reference device. It is deployed in the right or left atrium through an 8F guiding sheath. This deflectable catheter consists of a 4F circular spine on its distal tip, with platinum / iridium electrodes that can be used for stimulation and recording.

The LASSO 2515 NAV Variable Catheter features a Nitinol loop design that allows the expansion and contraction of the loop to custom-fit veins with different sizes, ranging from 25mm to 15mm diameter (± 15%).

The catheter interfaces with standard recording equipment via interface cables with the appropriate connectors.

5.3 Indications for Use:

The catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The LASSO 2515 NAV Variable Catheter is designed to obtain electrograms in the atrial regions of the heart.

The LASSO 2515 NAV Variable Catheter provides location information when used with compatible Carto EP Navigation Systems version 1.0 or higher.

5.4 Performance Data:

The Lasso 2515 NAV Variable Catheter underwent bench and animal testing. The Catheter passed all intended criteria in accordance with appropriate test criteria and standards.

5.5 Overall Performance Conclusions:

The nonclinical studies demonstrate that the Lasso 2515 NAV Variable Catheter is safe and effective for anatomic mapping of the heart and establish equivalence of the Lasso 2515 NAV Variable Catheter to the predicate devices, the Variable Lasso 2515 Circular Mapping Catheter and the NaviStar Diagnostic Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2009

Biosense Webster, Inc.
c/o Ms. Natalie Bennington
Manager, Regulatory Affairs
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K081258
Trade/Device Name: Lasso 2515 NAV Variable Catheter, D-1290-01 and D-1290-02
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II (two)
Product Code: DRF
Dated: November 25, 2008
Received: November 26, 2008

Dear Ms. Bennington:

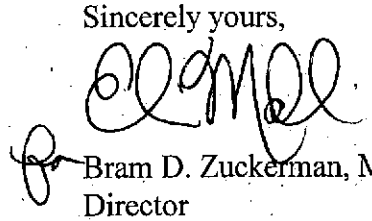
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081258

Device Name: Lasso 2515 NAV Variable Catheter, D-1290-01 & D-1290-02

Indications For Use:

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The LASSO 2515 NAV Variable Catheter provides location information when used with compatible Carto EP Navigation Systems version 1.0 or higher.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K081258